

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A method for determining the presence or absence of *Mycobacterium tuberculosis* (*M. tuberculosis*) in a biological sample, comprising

(a) ~~performing nucleic acid amplification amplifying a DNA segment using in the presence of~~ the nucleic acids from the biological sample as a template and a primer pair, suitable for amplifying a ~~wherein the amplified~~ DNA segment comprises comprising a region of SEQ ID NO:-1 that encompasses position -215, in the 5' to 3' direction of reading, upstream of the translation start codon GTG of the *narGHJI* nitrate reductase operon, and

(b) ~~determining in the amplification product of step (a), the presence or absence of the polymorphism specific for M. tuberculosis in position -215, in the 5' to 3' direction of reading, upstream of the translation start codon GTG of the narGHJI nitrate reductase operon, wherein the polymorphism specific for M. tuberculosis in position -215 is thymine (T), and wherein the presence of the polymorphism indicates the presence of M. tuberculosis in the biological sample, and the absence of the polymorphism indicates the absence of M. tuberculosis in the biological sample.~~

2. (Previously Presented) The method according to claim 1, wherein step (a) is carried out by polymerase chain reaction (PCR), nucleic acid sequence based amplification (NASBA), strand displacement amplification (SDA) or ligase chain reaction (LCR).

3. (Previously Presented) The method according to claim 2, wherein the PCR is a real time PCR.

4. (Previously Presented) The method according to any one of claims 1 to 3, wherein step (b) is carried out by hybridization of one or several probes.

5. (Previously Presented) The method according to any one of claims 1 to 3, wherein the DNA segment of step (a) has a length of 1 to 500 nucleotides.

6. (Previously Presented) The method according to any one of claims 1 to 3, wherein the DNA segment of step (a) has a length of 1 to 300 nucleotides.

7. (Previously Presented) The method according to any one of claims 1 to 3, wherein the DNA segment of step (a) has a length of 1 to 155 nucleotides.

8. (Previously Presented) The method according to any one of claims 1 to 3, wherein one primer of the primer pair of step (a) comprises SEQ ID NO: 2 or SEQ ID NO: 3.

9. (Previously Presented) The method according to any one of claims 1 to 3, wherein step (b) is carried out by means of at least one pair of labeled hybridization probes, one probe being labeled at its 3' end and the other probe being labeled at its 5' end, and the probes binding specifically to the DNA segment of step (a) in such a way that a fluorescence resonance energy transfer (FRET) is made possible.

10. (Currently Amended) The method according to claim 9, wherein one probe of the probe pair comprises SEQ ID NO:-4 and the other probe comprises SEQ ID NO:5; one probe of the probe pair comprises the complementary sequence of SEQ ID NO:4, and the other probe comprises the complementary sequence of SEQ ID NO:5; one probe of the probe pair comprises SEQ ID NO:-4 and the other probe comprises SEQ ID NO:6; or one probe of the probe pair comprises the complementary sequence of SEQ ID NO:4 and the other probe comprises the complementary sequence of SEQ ID NO:6.

11. (Previously Presented) The method according to any one of claims 1 to 3, wherein the sample is a clinical sample selected from the group consisting of saliva, bronchial lavage, gastric juice, urine, faeces, liquor, bone marrow, blood and biopsies.

12.-18. (Canceled)

19. (Currently Amended) A hybridization probe for detecting the polymorphism specific for *M. tuberculosis* located in position -215 in the 5' to 3' direction of reading upstream of the translation start codon GTG of the *narGHJI* nitrate reductase operon, wherein the polymorphism specific for M. tuberculosis in position -215 is thymine (T).

20. (Currently Amended) A hybridization probe pair for detecting the polymorphism specific for *M. tuberculosis* located in position -215 in the 5' to 3' direction of reading upstream of the translation start codon GTG of the *narGHJI* nitrate reductase operon, wherein the polymorphism specific for M. tuberculosis in position -215 is thymine (T).

21. (Currently Amended) The hybridization probe pair according to claim 20, wherein one probe of the probe pair comprises SEQ ID NO:-4 or the complementary sequence thereof.

22. (Currently Amended) The hybridization probe pair according to claim 20, wherein one probe of the probe pair comprises SEQ ID NO:-5 or the complementary sequence thereof.

23. (Currently Amended) The hybridization probe pair according to claim 20, wherein one probe of the probe pair comprises SEQ ID NO:-6 or the complementary sequence thereof.

24. (Currently Amended) The hybridization probe pair according to claim 20, wherein one probe in the probe pair comprises SEQ ID NO:-4 and the other probe comprises

SEQ ID NO:-5, or one probe in the probe pair comprises the complementary sequence of SEQ ID NO:4 and the other probe comprises the complementary sequence of SEQ ID NO:5.

25. (Currently Amended) The hybridization probe pair according to claim 20, wherein one probe in the probe pair comprises SEQ ID NO:-4 and the other probe comprises SEQ ID NO:-6, or one probe in the probe pair comprises the complementary sequence of SEQ ID NO:4 and the other probe comprises the complementary sequence of SEQ ID NO:6.

26. (Currently Amended) A hybridization probe comprising SEQ ID NO:-4 or the complementary sequence thereof.

27. (Currently Amended) A hybridization probe comprising SEQ ID NO:-5 or the complementary sequence thereof.

28.-30. (Canceled)

31. (Currently Amended) A kit for detecting *M. tuberculosis*, comprising:
at least one primer pair suitable for amplifying a DNA segment from SEQ ID NO: 1, wherein the DNA segment comprises position -215 in the 5' to 3' direction of reading upstream of the translation start codon GTG of the *narGHJI* nitrate reductase operon, or

at least one hybridization probe or a hybridization probe pair suitable for detecting the polymorphism specific for *M. tuberculosis* located in position -215 in the 5' to 3' direction of reading upstream of the translation start codon GTG of the *narGHJI* nitrate reductase operon,

wherein the polymorphism specific for *M. tuberculosis* in position -215 is thymine (T).

32. (Previously Presented) The kit according to claim 31, wherein one primer of the primer pair comprises SEQ ID NO:2 and the other primer comprises SEQ ID NO:3.

33. (Currently Amended) The kit according to claim 31, wherein
- (a) one probe in the hybridization probe pair comprises SEQ ID NO:4 and the other probe in the probe pair comprises SEQ ID NO:5;
 - (b) one probe in the hybridization probe pair comprises the complementary sequence of SEQ ID NO:4 and the other probe in the probe pair comprises the complementary sequence of SEQ ID NO:5;
 - (c) one probe in the hybridization probe pair comprises SEQ ID NO:4 and the other probe in the probe pair comprises SEQ ID NO:6; or
 - (d) one probe in the hybridization probe pair comprises the complementary sequence of SEQ ID NO:4 and the other probe in the probe pair comprises the complementary sequence of SEQ ID NO:6.

34. (Previously Presented) The kit according to claim 33, wherein one primer of the primer pair comprises SEQ ID NO:2 and the other primer of the primer pair comprises SEQ ID NO:3.

35. (Currently Amended) The kit according to claim 31 or claim 32, further comprising reagents or auxiliary agents ~~necessary or useful~~ for carrying out a nucleic acid amplification or detection reaction.

36. (Currently Amended) A method for determining the presence or absence of *Mycobacterium tuberculosis* (*M. tuberculosis*) in clinical material, comprising

- a) extracting microbial DNA from clinical material,
- b) amplifying from performing nucleic acid amplification in the presence of the extracted DNA and a primer pair suitable for amplifying at least one a DNA fragment of the promoter region of the *narGHJI* nitrate reductase operon of mycobacteria containing at least one DNA polymorphism specific for M. tuberculosis the nucleotide located in position -215 of the promoter region, in the 5' to 3' direction of reading, upstream of the translation start codon GTG of the *narGHJI* mitrate reductase operon, and

c) determining in the amplification product of step (b), the presence or absence of the specific hybridization of the DNA fragment of step (b) polymorphism specific for *M. tuberculosis* in position -215 by way of melting curve analysis with at least one hybridization probe that comprises the nucleotide sequence selected from the group consisting of SEQ ID NO: 5, the complementary sequence to SEQ ID NO:-5, SEQ ID NO:-6, and the complementary sequence to SEQ ID NO:-6,

wherein the presence of the specific hybridization polymorphism specific for *M. tuberculosis* in position -215 indicates the presence of *M. tuberculosis* in the clinical material, and the absence of the polymorphism specific for *M. tuberculosis* in position -215 specific hybridization indicates the absence of *M. tuberculosis* in the clinical material, and

wherein the polymorphism specific for *M. tuberculosis* in position -215 is thymine (T).

37. (Canceled)

38. (Currently Amended) The method according to claim 3736, wherein step b) is carried out by means of a primer pair having one primer that comprises SEQ ID NO:-2 and the other primer comprises SEQ ID NO:-3.

39. (Currently Amended) The method according to any one of claims 36 to or claim 38, wherein step c) is carried out with at least one pair of labeled hybridization probes, and wherein one probe of the pair comprises SEQ ID NO:-4 and the other probe comprises SEQ ID NO:-5, one probe of the pair comprises the complementary sequence of SEQ ID NO:4 and the other probe comprises the complementary sequence of SEQ ID NO:5, one probe of the pair comprises SEQ ID NO:4 and the other probe comprises SEQ ID NO:6, or one probe of the pair comprises the complementary sequence of SEQ ID NO: 4 and the other probe comprises the complementary sequence of SEQ ID NO: 6.

40. (Currently Amended) The method according to any one of claims 36 to or claim 38, wherein step (b) is carried out by polymerase chain reaction (PCR).

41. (Currently Amended) The method according to ~~any one of claims 36 to or~~
~~claim 38~~, wherein step (c) is carried out during or after step (b).

42. (Currently Amended) The method according to ~~any one of claims 36 to or~~
~~claim 38~~, wherein step (c) is carried out via real time PCR.

43. (Currently Amended) The method according to ~~any one of claims 36 to or~~
~~claim 38~~, wherein step (c) is carried out by fluorescence detection, and the labeled hybridization probe pairs are formed as fluorescence resonance energy transfer (FRET) pair.

44. (Currently Amended) The method according to ~~any one of claims 36 to or~~
~~claim 38~~, wherein the clinical material is selected from the group of clinical samples consisting of saliva, bronchial lavage, gastric juice, urine, faeces, liquor, bone marrow, blood and biopsies.

45. (Canceled)

46. (Currently Amended) An oligonucleotide which hybridizes specifically with an *M. tuberculosis*-specific promoter region of the *narGHJI* nitrate reductase operon, comprising SEQ ID NO:-5 or the complementary sequence thereof.

47. (Currently Amended) An oligonucleotide which hybridizes specifically with an *M. tuberculosis*-specific promoter region of the *narGHJI* nitrate reductase operon, comprising the nucleotide sequence SEQ ID NO:-6 or the complementary sequence thereof.

48. (Currently Amended) An oligonucleotide pair, wherein one oligonucleotide in the pair comprises SEQ ID NO:-4 and the other oligonucleotide comprises SEQ ID NO:-5, or one oligonucleotide in the pair comprises the complementary sequence of SEQ ID NO:4 and the other oligonucleotide comprises the complementary sequence of SEQ ID NO:5.

49. (Currently Amended) An oligonucleotide pair, wherein one oligonucleotide in the pair comprises SEQ ID NO:-4 and the other comprises SEQ ID NO:-6, or one oligonucleotide in the pair comprises the complementary sequence of SEQ ID NO:4 and the other comprises the complementary sequence of SEQ ID NO:6.

50. (Previously Presented) A kit for detecting *Mycobacterium tuberculosis* comprising

a) at least one primer pair, wherein one primer in the primer pair comprises SEQ ID NO: 2, and the other primer comprises SEQ ID NO: 3 and

b) at least one hybridization probe pair, wherein one probe in the probe pair comprises SEQ ID NO: 4 and the other probe comprises SEQ ID NO: 5, one probe in the probe pair comprises the complementary sequence of SEQ ID NO:4 and the other probe comprises the complementary sequence of SEQ ID NO:5, one probe in the probe pair comprises SEQ ID NO: 4 and the other probe comprises SEQ ID NO: 6, or one probe in the probe pair comprises the complementary sequence of SEQ ID NO:4 and the other probe comprises the complementary sequence of SEQ ID NO:6.

51. (Currently Amended) The method of claim 36, wherein the at least one hybridization probe in step (c) comprises SEQ ID NO:-6 or the complementary sequence thereof.

52. (Previously Presented) The method according to claim 1, wherein one primer of the primer pair of step (a) comprises SEQ ID NO:2.

53. (Previously Presented) The method according to claim 1, wherein one primer of the primer pair of step (a) comprises SEQ ID NO:3.

54. (Previously Presented) The method according to claim 1, wherein one primer of the primer pair of step (a) comprises SEQ ID NO:2 and the other primer comprises SEQ ID NO:3.

55. (New) The hybridization probe of claim 19, wherein the hybridization probe hybridizes to (a) a region of SEQ ID NO:7 or SEQ ID NO:8 that encompasses position -215, or (b) the complement of the region of SEQ ID NO:7 or SEQ ID NO:8 that encompasses position -215.

56. (New) The hybridization probe pair of claim 20, wherein one of the hybridization probe pair hybridizes to (a) a region of SEQ ID NO:7 or SEQ ID NO:8 that encompasses position -215, or (b) the complement of the region of SEQ ID NO:7 or SEQ ID NO:8 that encompasses position -215.

57. (New) A hybridization probe comprising SEQ ID NO:6 or the complementary sequence thereof.

58. (New) The hybridization probe of claim 26, wherein the probe is at most 50 nucleotides in length.

59. (New) The hybridization probe of claim 27, wherein the probe is at most 50 nucleotides in length.

60. (New) The hybridization probe of claim 57, wherein the probe is at most 50 nucleotides in length.